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APPLICANT(s):
Stahly et al.

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U.S. PATENT DOCUMENTS FILING DATE **EXAMINER** DOCUMENT DATE NAME **CLASS** IF INITIAL APPROPRIATE NO. 4,290,835 09/22/81 Yates et al. 156 601 2 10/20/81 Schuler et al. 23 4,295,857 301 5,363,797 11/15/94 117 3 Uenishi et al. 68 70 4 5,997,636 12/07/99 Gamarnik et al. 117

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL	DOCUMENT NO.	PUBLICATION DATE	COUNTRY	CLASS	SUBCLASS	TRANSLA	TION
HATTE	110.	DATE				YES	NO

	OTHE	R DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
V /	5	Cristian, et al., "The Mechanism of Material Drying v. Liquid Evaporation From
16	1	Capilaries," Buletinul Institutului Politehnic Din Iasi, Sectia II, pp. 37-43, 1979
	6	Overman, et al., "Convective Diffusion in Capillaries," The Journal of Physical
	1	Chemistry, Volume 72, Number 1, pp. 155-158, January 1968
	7	Preiss, et al., "Evaporation From A Capillary Tube," Transactions of the ASME,
	,	Journal of Heat Transfer, pp. 178-181, May 1976
	8	Christenson, et al., "Growth of Ionic Crystallites on Exposed Surfaces," Journal of Colloid and Interface Science, Vol. 117, No. 2, pp. 576-577, June 1987
	9	Sibille, et al., "Analysis of solvent evaporation rates in the vapor diffusion protein
	,	crystal growth experiments from STS-61C Space Shuttle Mission," <i>Journal of Crystal Growth</i> , 110, pp. 72-79, 1991
34 11/11	10	Sibille, et al., "Solvent evaporation rates in the enclosed capillary vapor diffusion
\bigvee	/	method of protein crystal growth," Journal of Crystal Growth, 110, pp. 80-88, 1991

Heil

DATE CONSIDERED:

06/20/03

S. DEPARTMENT OF COMMERCE AFFICE AFFICE

ATTY. DOCKET NO.
13001US01
APPLICANT(s):
Stahly et al.

SERIAL NO. 3 69/752(837

INFORMATION SCLOSURE CITATION

DEMAN eral sheets if necessary)

FILING DATE
December 28, 2000

OROUP ARP UNIT

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
		11	Swanson, et al., "Model of the Evaporating Meniscus in a Capillary Tube,"			
11	/		Transactions of the ASME, Journal of Heat Transfer, Vol. 114, pp. 434-441, May			
Y	h	/	1992			
	ν					
		12	Stewart, et al., "The Formation of Particle Clusters Near An Interfacial Meniscus,"			
l i			Chemical Engineering Science, Vol. 48, No. 4, pp. Vol. 771-788, 1993			
		/	Chemical Engineering Science, von 10, 1101 1, pp. von 171 100, 1330			
	<u> </u>	13	Laurindo, et al., "Evaporation in Capillary Porous Media. An Experimental and			
		13	Numerical Network Study," Proceedings of the ASME Heat Transfer and Fluids			
İ	1	/	Engineering Divisions, HTD-Vol. 321, FED-Vol. 233, pp. 637-649, 1995			
			751 . 1 . 1 . 1 . 1 . 1 . 1 . 1 . 1 . 1 .			
	ľ	14	Khrustalev, et al., "Fluid Flow Effects in Evaporation From Liquid-Vapor Meniscus,"			
	ĺ		Transactions of the ASME, Journal of Heat Transfer, Vol. 118, pp. 725-730, August			
		. ,,,,	1996			
		15	Kuz, "Model for the Convective Transport of Particles in a Two-Dimensional Cluster,"			
	1		American Chemical Society, Langmuir, 13, pp. 3900-3901, 1997			
		/				
		16	Douglas, et al., "Wetting of a Chemically Heterogeneous Surface," Journal of			
			Chemical Physics, Vol. 110, No. 12, pp. 5969-5977, 22 March 1999			
		`	Chemical 1 1/30002, 1 of 120, 110 122, pp. 0505 0511, 22 122201 2555			
		17	Amaro-Gonzalez, et al., "Gas antisolvent crystallization of organic salts from aqueous			
	ļ	''	solutions," The Journal of Supercritical Fluids, 17, pp. 249-258 (2000).			
		•	Solutions, The Souther of Supercritical Latias, 17, pp. 245 250 (2000).			
		18	Mullin, "Crystallization Techniques and Equipment," Crystallization, Butterworth-			
		10				
			Heinemann, pp. 265-368, 1993			
\vdash		10				
		19	Guillory, "Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids,"			
			Polymorphism in Pharmaceutical Solids, pp. 183-226, Marcel-Dekker, Inc. 1999			
		_				
		20	He, et al., "Conformational Color Polymorphism and Control of Crystallization of 5-			
Y	1/		Methyl-2-[(4-methyl-2-nitrophenyl)amino]-3-thiophenecarbonitrile," Journal of			
	V		Pharmaceutical Sciences, Vol. 90, No. 3, pp. 371-388, March 2001			
	-					
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EXAMINER

Lale

DATE CONSIDERED:

06/20/02

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.
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INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

1000		ОТНЕ	R DOCUMENTS (Including Author, Title, Date, Pertinent Pages,
PATEN	TADEURKK.	21	Beckmann, et al., "Occurrence, Stability, Kinetics of Crystallization and Polymorphic Transition of the A, B and C Modification of Abecarnil, Influence of Supersaturation, Temperature, Solvents and Impurities," <i>Institution of Chemical Engineers Trans IChemE</i> , Vol. 74, Part A, pp. 750-758, October 1996
PAIEN			Yu, et al., "Thermochemistry and Conformational Polymorphism of a Hexamorphic Crystal System," <i>Journal of American Chemical Society</i> , 122, No. 4, pp. 585-591, 2000
		23	Stephenson et al., "Conformational and Color Polymorphorism of 5-Methyl-2-[(2-nitrophenyl)amino]-3-thiophenecarbonitrile," <i>Journal of Pharmaceutical Sciences</i> , Vol. 84, No. 11, pp. 1385-1386, November 1995
		24 i	Moore, et al., "Crystal and Molecular Structures of Two Polymorphs of 4-Methyl-2-Nitroacetanilide (MNA)," <i>Journal of Crystallographic and Spectroscopic Research</i> , Vol. 13, No. 4, pp. 279-292, 1983
		25	Moore, et al., "Crystal and Molecular Structure of an Amber Polymorph of 4-Methyl-2-Nitroacetanilide (MNA)," <i>Journal of Crystallographic and Spectroscopic Research</i> , Vol. 14, No. 3, pp. 283-291, 1983
		26	Singh, et al., "Solid-State Characterization of Chlordiazepoxide Polymorphs," <i>Journal of Pharmaceutical Sciences</i> , Vol. 87, No. 5, pp. 655-662, May 1998
		27	Harris, et al., "'Polymorphism' in a Novel Anti-Viral Agent: Lamivudine," Journal of Chemical Society, Perkin Trans., 2, pp. 2653-2659, 1997
		28	Caira, et al., "Crystal and Molecular Structures of Three Modifications of the Androgen Dehydroepiandrosterone (DHEA)," <i>Journal of Chemical Crystallography</i> , Vol. 25, No. 7, pp. 393-400, 1995
	4	29	Cox, et al., "Structure of 3ß-Hydroxy-5-androsten-17-one (DHEA) Monohydrate," International Union of Crystallography, pp. 334-336, 1990

EXAMINER

DATE CONSIDERED:

06/20/02

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.
13001US01
APPLICANT(s):
Stahly et al.

SERIAL NO. 09/752,85

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INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

FILING DATE
December 28, 2000

GROUP RT UNIT:

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
Survey.	TO THE SAME OF THE PARTY OF THE	30	Chao, et al., "Polymorphism of 1,2-Dihydro-6-neopentyl-2-oxonicotinic Agai: Characterization, Interconversion, and Quantitation," <i>Pharmaceutical Research</i> , Vol.		
\$ YE	DEMAR	/	4, No. 5, pp. 429-432, 1987		
2	ENT & THE	31	Gavezzotti, et al., "Polymorphic Forms of Organic Crystals at Room Conditions:		
PAT	EN	,	Thermodynamic and Structural Implications," <i>Journal of American Chemical Society</i> , 117, pp. 12299-12305, 1995		
		`	· · · · · · · · · · · · · · · · · · ·		
		32	Henck, et al. "Polymorphism of Tedisamil Dihydrochloride," Journal of		
		,	Pharmaceutical Sciences, Vol. 89, No. 9, pp. 1151-1159, September 2000		
		33	Nomura, et al., "Thermal Polymorphic Transformation of <i>p-tert</i> -Butylcalix[4]arene		
			Derivatives Bearing Amino Acid Substituents," <i>Journal of Organic Chemistry</i> , Vol. 65, No. 19, pp. 5932-5936, 2000		
		/	140. 15, pp. 3532-3530, 2000		
		34	Gavezzotti, "A Molecular Dynamics Test of the Different Stability of Crystal		
	:	•	Polymorphs under Thermal Strain," <i>Journal of American Chemical Society</i> , 122, pp. 10724-10725, 2000		
		35	Dinnebier, et al., "Structural Characterization of Three Crystalline Modifications of		
			Telmisartan by Single Crystal and High-Resolution X-ray Powder Diffraction," <i>Journal of Pharmaceutical Sciences</i> , Vol. 89, No. 11, pp. 1465-1479, November 2000		
		1	of That material Betefaces, Vol. 65, 110. 11, pp. 1105 1175, 110 ventoer 2000		
		36	Henck, et al., "Disappearing and Reappearing Polymorphs. The Benzocaine:Picric		
			Acid System," Journal of American Chemical Society, 123, pp. 1834-1841, 2001		
	-	37	Threlfall, "Analysis of Organic Polymorphs, A Review," Analyst, 120, pp. 2435-2448,		
		ß	October 1995		
	7	38	Spruijtenburg, "Examples of the Selective Preparation of a Desired Crystal		
Y		,	Modification by an Appropriate Choice of Operating Parameters," Organic Process		
1 4		į	Research & Development, 4, pp. 403-406, 2000		
u			l		

EXAMINER

Hali

DATE CONSIDERED:

06/20/0

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.
13001US01
APPLICANT(s):
Stahly et al.
FILING DATE

December 28, 2000

SERIAL NO. 09/752,85

GROUP ART UNIT

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Beckmann, "Seeding the Desired Polymorph: Background, Possibilities, Limitations, and Case Studies," Organic Process Research & Development, Vol. 4, pp. 372-383, 2000 Threfall, "Crystallization of Polymorphs: Thermodynamic Insight into the Role of 40 Solvent," Organic Process Research & Development, 4, pp. 384-390, 2000 Vrcelj, et al., "Polymorphism in 2,4,6-Trinitrotoluene Crystallized from Solution," 41 Journal of American Chemical Society, 123, pp. 2291-2295, 2001 Caira, et al., "Structural Characterization of Two Polymorphic Forms of Piroxicam 42 Pivalate, " Journal of Pharmaceutical Sciences, Vol. 87, No. 12, pp. 1608-1614, December 1998 Gu, et al., "Characterization of Polymorphic Forms of Fluconazole Using Fourier 43 Transform Raman Spectroscopy," Journal of Pharmaceutical Sciences, Vol. 84, No. 12, pp. 1438-1441, December 1995 Salem, et al., "Preparation, Characterization and Transformation of Terfenadine 44 Polymorphic Forms, "International Journal of Pharmaceutics, 141, pp. 257-259, 1996 Hassan, et al., "Characterization of Famotidine Polymorphic Forms," International 45 Journal of Pharmaceutics, 149, pp. 227-232, 1997 Ghodbane, et al., "Study of the polymorphism of 3-(((3-(2-(7-chloro-2-quinolinyl)-(E)-46 ethenyl)phenyl)((3-(3-(dimethylamino-3-oxopropyl)thio)methyl)-thio)propanoic acid (MK571) by DSC, TG, XRPD and Solubility Measurements," International Journal of Pharmaceutics, 59, pp. 281-286, 1990 Pienaar, et al., "Polymorphs of Nitrofurantoin. 2. Preparation and X-ray Crystal 47 Structures of Two Anhydrous Forms of Nitrofurantoin," Journal of Crystallographic and Spectroscopic Research, Vol. 23, No. 10, 785-790, 1993

EXAMINER				
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DATE CONSIDERED:

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Form PTO-1449
(Rev. 8-83)
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INFORMATION DISCLOSURE CITATION

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ATTY. DOCKET NO. 13001US01

SERIAL NO. 09/752,857

APPLICANT(s): Stahly et al.

FILING DATE December 28, 2000 GROUE

C181 300 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Giordano, et al., "Crystal Forms of Piroxicam Pivalate: Preparation and Characterization of Two Polymorphs," Journal of Pharmaceutical Sciences, Vol. 87, No. 3, pp. 333-346, March 1998 Bartolomei, et al., "Solid-State Investigation of Fluocinolone Acetonide," Journal of 49 Pharmaceutical and Biomedical Analysis, 15, pp. 1813-1820, 1997 Kiss, et al., "Solid State Investigation of Mefloquine Hydrochloride," Journal of 50 Pharmaceutical & Biomedical Analysis, Vol. 12, No. 7, pp. 889-893, 1994 Caira, et al., "Structure and Thermal Stability of Alprazolam and Selected Solvates," 51 Journal of Pharmaceutical Sciences, Vol. 84, No. 11, pp. 1379-1384, November 1995 Wu, et al., "Investigation of Moricizine Hydrochloride Polymorphs," Journal of 52 Pharmaceutical Sciences, Vol. 83, No. 10, pp. 1404-1406, October 1994 53 Hildebrand, et al., "Ketoprofen Sodium: Preparation and Its Formation of Mixed Crystals with Ketoprofen," Journal of Pharmaceutical Sciences, Vol. 86, No. 7, 854-857, July 1997 Agafonov, et al., "Polymorphism of Spironolactone," Journal of Pharmaceutical 54 Sciences, Vol. 80, No. 2, pp. 181-185, February 1991 Singh, et al., "Solid-State Characterization of Chlordiazepoxide Polymorphs," Journal 55 Pharmaceutical Sciences, Vol. 87, No. 5, p. 655, May 1998 ť Chang, et al., "Solid State Characterization of Dehydroepiandrosterone," Journal of 56 Pharmaceutical Sciences, Vol. 84, No. 10, pp. 1169-1179, October 1995 Tros de Ilarduya, et al., "Polymorphism of Sulindac: Isolation and Characterization of 57 a New Polymorph and Three New Solvates," Journal of Pharmaceutical Sciences, Vol. 86, No. 2, pp. 248-251, February 1997

EXAMINER

DATE CONSIDERED

Form/PTO-1449 (Rev. 8-83) (modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 13001US01	SERIAL NO. 09/752,857
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i	several sheets if necessary)	FILING DATE December 28, 2000	GROUP ART UNIT:

Ţ	JC181 30/J	OTHE	R DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	3 2001	58	Stephenson, et al., "Solid-State Analysis of Polymorphic, Isomorphic, and Solvated
	120	PADEMA	Forms of Dirithromycin," <i>Journal of American Chemical Society</i> , 116, pp. 5766-5773, 1994
1	F S	<i>'</i>	
	Paren	59	Byrn et al., "Solid-State Chemistry of Drugs," SSCI, Inc., Second Edition, pp. 1-574, 1999
			1999 A
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			C 3200, O

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DATE CONSIDERED:

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